510(k) SUMMARY
Cayman MI Plates
K2M, Inc.

1. Submitter :
K2M, Inc.
751 Miller Drive SE,
Leesburg, VA 20175

Contact Person :
Nancy Giezen
K2M, Inc.
Telephone: 703-777-3155

Date Prepared: October 16, 2013

NOV 0 9 2013

2. Tradename: Cayman Plate System
Common Name: Thoracolumbar Plates
Classification Name: Spinal intervertebral body fixation orthosis (21 CFR 888.3060)
Product Code: KWQ

3. Predicate or legally marketed devices which are substantially equivalent :

- K2M Cayman Plate System, K081380, K091253, K100061
- DePuy Aegis, K052546
- DePuy M2, K972718
- Sofamor Danek, Z-Plate, K922543

4. Description of the device:

The Cayman Plate System is a spinal fixation system which consists of screws and plates. All of the components are available in a variety of sizes to more closely match the patient's anatomy.

Materials: The devices are manufactured from CP Titanium and Ti6Al4V per ASTM and ISO standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of the spine.

The purpose of this submission is to add minimally invasive (MI) plates.

5. Intended Use:

The CAYMAN Buttress Plates are intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

The CAYMAN Thoracolumbar Plates are indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures (L5-S1). The Cayman Thoracolumbar Plate System is intended to provide temporary stabilization during fusion using autograph or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities and deformities: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h) lordotic deformities of the spine, i) thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy.

6. Technological and Performance Characteristics:

The Cayman Thoracolumbar Plates were previously tested in static compression bending, dynamic compression testing and static torsion and were considered substantially equivalent to other legally marketed devices. Additional ASTM F1717 testing determined that the proposed MI plates do not represent a new worst case. They are similar in design, material, and indications for use to predicate plates and are expected to be equivalent in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 9, 2013

K2M, Incorporated
Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive, Southeast, Suite F1
Leesburg, Virginia 20175

Re: K131533
Trade/Device Name: Cayman Thoracolumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 17, 2013
Received: October 18, 2013

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131533

Device Name: Cayman Thoracolumbar Plate System

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Prescription Use X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-counter Use __ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices